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Summary of Safety and Effectiveness

Hoffmann® II Compact™ MRI External Fixation System

Proprietary Name: Hoffmann® II Compact™ MRI External Fixation System

Common Name: External Fixation Frame Components

Classification Name and Reference Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030

Device Product Code: 87 KTT, 87 LXT & 87 JEC

For Information contact: Vivian Kelly, Regulatory Affairs Specialist
Howmedica Osteonics Corp.
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Date Summary Prepared: October 25, 2005

Description:

This Special 510(k) submission is intended to address modifications to the predicate Hoffmann® II Compact™ External Fixation Systems to include MRI conditional components for use in Magnetic Resonance Imaging (MRI) procedures under predetermined conditions

Intended Use:

The subject and predicate devices are external fixation frames intended to provide stabilization of open and/or unstable fractures of the upper and lower extremities.

Indications for Use:

The Hoffmann® II Compact™ MRI components are intended to be used with the Half Pins or Transfixing Pins of the Hoffmann® External Fixation System and the components of the Hoffmann® II External Fixation System. It is intended to be used in the stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting, and other means of internal fixation.

Substantial Equivalence:

The subject Hoffmann® II Compact™ MRI components share the same intended use, and basic design concepts as that of the currently available Hoffmann® II Compact™ External Fixation System. Mechanical testing demonstrated comparable mechanical properties to the predicate components and testing in a Magnetic Resonance Environment established that the components could be safely used in MRI diagnostic procedures under predetermined conditions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2005

Vivian Kelly
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K053038

Trade/Device Name: Hoffman® II Compact™ MRI External Fixation Systems

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances
and accessories

Regulatory Class: II

Product Code: KTT, JEC, LXT

Dated: October 25, 2005

Received: October 27, 2005

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053038

Device Name: Hoffmann® II Compact™ MRI External Fixation Systems

Indications for Use:

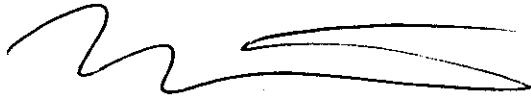
The Hoffmann® II Compact™ MRI components are intended to be used with the Half Pins or Transfixing Pins of the Hoffmann® External Fixation System and the components of the Hoffmann® II External Fixation System. It is intended to be used in the stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting, and other means of internal fixation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

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